

Frequently Asked Questions - Other

If home health agencies assist patients in their homes to self test, do they need a CLIA certificate?

It depends. If the nurse or employee only assists the patients and provides the patients self testing result to the doctor, a certificate is not required. If the nurse or employee conducts the test, a certificate is required.

In Nebraska - is a phlebotomist required to have a CLIA certificate and license?

No. Phlebotomists are not required to be licensed in the state of Nebraska or have a CLIA certificate to draw blood samples.

Do I need to have a CLIA certificate to send clinical samples to other state(s) for testing?

No, but samples can only be sent to a CLIA certified laboratory that is in good standing and with a current CLIA certificate.

I am an out of state laboratory. Do I need a CLIA certificate or permit to receive and test specimens from Nebraska?

No. The requirements are for your facility to be CLIA certified and in good standing; however, you must provide instructions for specimen collection, processing and a copy of your CLIA certificate to the submitter(s).

We only draw blood samples that are sent to a lab for testing. Do we need a CLIA certificate?

If laboratory tests are **NOT** performed, a CLIA certificate is not required.

Are specimen collection sites allowed in the state of Nebraska, and do they need a CLIA certificate?

Independent collections sites do not require a CLIA certificate.

I do not bill Medicare or Medicaid for laboratory tests. Do I need a CLIA certificate?

If you perform any category of laboratory tests, such as CLIA Waived, PPM (Provider Performed Microscopy) or non-waived (moderate or high complexity), you are required to have a CLIA certificate. Billing has nothing to do with whether or not you need a CLIA certificate.

What is a CLIA waived test? A PPM test? And a non-waived test?

CLIA waived tests are categorized as "simple laboratory examinations and procedures that have an insignificant risk of an erroneous result."

A PPM test is a microscopy examination in which a physician, midlevel practitioner or dentist performs specific microscopy procedures during the course of a patient's visit. These tests are categorized as moderate complexity.

A non-waived test is a laboratory test procedure that can be either moderate and/or high complexity. The test complexity is determined by the Food and Drug Administration (FDA).

Where can I find a list of CLIA waived, PPM and non-waived tests?

The most current lists can be found by visiting the CMS CLIA website and clicking on the link, 'Categorization of Tests.'

How can I find if a test is moderate, high complexity, waived or non-waived?

- You may call the vendor of the test(s). The FDA provides that information to the vendors.

- You may visit the FDA website. The site will help you determine the tests categorization as waived or non-waived (i.e., moderate or high complexity).

Where can I find information about CLIA laboratory personnel qualifications?

Information can be found on this website under "Laboratory Personnel Qualifications" or by visiting the CMS CLIA website.

What type of tests can I perform under each type of laboratory certificate?

- **CLIA waived certificate** allows the facility to perform only tests categorized as CLIA waived.
- **CLIA PPM certificate** allows the facility to perform CLIA waived and PPM tests.
- **CLIA certificate of compliance (COC) or accreditation (COA)** allows the laboratory to perform CLIA waived, PPM and non-waived (moderate and/or high complexity) tests.

Where do I find the CMS-116 form?

The CLIA application (Form CMS-116) is available on this website under CHANGES or by visiting the CMS CLIA website.

When can I begin testing?

You may begin testing once you receive your CLIA certificate.

Will my laboratory receive a survey inspection?

If your application is for a CLIA certificate of compliance or accreditation, you will be inspected. First, you will receive a temporary certificate of registration and should begin testing once received, which will allow you to establish your laboratory records that will be reviewed during the inspection. If you applied for a certificate of compliance, you will be inspected by the CLIA Program in between three to twelve months. If you applied for a certificate of accreditation, you will be inspected by the accrediting agency at their discretion and before your certificate of registration expiration date. After inspection and you are in compliance, a billing statement will be sent to your facility for your Certificate of Compliance or Certificate of Accreditation. Once paid, your new certificate will be issued.

If I have more than one laboratory at different addresses, do I need a CLIA certificate for each location?

Yes, certificates are issued per location.

Is it possible to have one CLIA certificate and perform temporary testing at different locations?

If you meet the CMS exception 1, you may request an endorsement for temporary testing in your certificate.

CMS Exception 1: Laboratories that are not at a fixed location, that is, laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs or other temporary testing locations may be covered under the certificate of the designated primary site or home base, using its address.

We are a home health agency that employs 15 nurses that will perform waived testing in patients' homes. What type of certificate is required?

Your facility meets CMS – Exception 1 and can be issued a single certificate of waiver. You may request that by completing a new CMS-116 application that can be found on this website. The home base for your certificate will be the address where your agency is located and the patients' homes will be considered as the temporary testing sites.

We are not-for-profit. Can we have multiple laboratory locations under the same CLIA Certificate?

If you meet the not-for-profit CMS exception, you may register all your laboratories under one certificate.

CMS Exception 2:

- Your facility must either be not-for-profit, a federal, a state or local government.
- Not-for-profit federal 501(c) (3) tax determination letter must be included with your application.
- You can only perform a total of 15 different tests, which can be all waived, moderate or a combination of both.
- All labs under the certificate may only perform tests within the 15 tests listed on the CMS-116 application.

We are a university with hospital. Can we have multiple laboratories under the same CLIA certificate?

Under CMS Exception 3 for hospitals: A single certificate to cover all of the hospital satellite laboratories may be issued, providing that all of the satellite labs are located at contiguous buildings on the same campus or within the same physical location or street address as the hospital and are under the same laboratory director, OR a separate certificate may be issued for each of the satellite laboratories based on the type of testing performed. **The hospital exception stands alone and cannot be mixed or combined with other CMS exceptions.**

Can I share my CLIA certificate and laboratory with other physicians practicing in the same location?

If you meet the following criteria, you may share your certificate and lab:

1. A shared laboratory is located in a common area.
2. Two or more sole practicing physicians or group practices share the expenses necessary to operate the laboratory.
3. Laboratory testing in a shared laboratory is directed by one qualified individual who is responsible for the overall operation, quality assurance and administration of the laboratory.
4. Independent practices sharing the certificate can **ONLY** perform the test complexity or category allowed under the shared laboratory CLIA certificate.

Facilities performing tests at a different location and not in the shared laboratory testing area will require their own CLIA certificate.

To declare your certificate as shared, you may use forms available on this website under FORMS.

Is it possible to have two CLIA certificates in the same testing location?

If the following conditions are met, two entities may operate in the same site with separate CLIA numbers:

- The times must be shown for each laboratory's operation.
- Each laboratory must have a unique name and directed by a different laboratory director.
- Each laboratory must maintain entirely separate records and demonstrate independent operation.
- Each laboratory test reports must clearly identify the laboratory that performed the test.
- Each laboratory must develop policies to prevent proficiency testing sample sharing or information between the two labs.
- If applicable, each laboratory (CLIA number) should enroll in a separate proficiency testing program using different proficiency testing providers. You may request an additional certificate by using forms available on this site under FORMS.

I am no longer performing laboratory testing. How can I cancel my certificate?

You may cancel your certificate by sending a written signed notification (including the CLIA Certificate #) to the Nebraska CLIA Program or the Nebraska CLIA Change Form found under FORMS.

I need to change my Tax ID on the CLIA certificate. How can I do that?

You can change your Tax ID by completing a Nebraska CLIA Change Form and the CLIA Ownership Information form that can be found on this website under FORMS.